

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
1:25-cv-00368**

United Therapeutics Corporation,

Plaintiff,

v.

Liquidia Technologies, Inc.,

Defendant.

**DEFENDANT LIQUIDIA TECHNOLOGIES, INC.'S
OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION**

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TABLE OF ABBREVIATIONS

Abbreviation	Full Term
TRO	Temporary Restraining Order
TRO hearing	May 20, 2025, Temporary Restraining Order hearing
UTC	United Therapeutics Corporation
Liquidia	Liquidia Technologies, Inc.
FDA	Food and Drug Administration
DJ	Declaratory Judgment
<i>Hatch-Waxman-II</i>	<i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , No. 23-cv-975-RGA (D. Del.)
<i>APA II</i>	<i>Liquidia Techs., Inc. v. FDA</i> , No. 1:24-cv-02428 (D.D.C.)
'782 patent	Patent No. 11,357,782 (DE 1, Ex.A)
'793 patent	Patent No. 10, 716,793
Motion	UTC's Motion for Temporary Restraining Order and Preliminary Injunction
PTAB	United States Patent Trial and Appeal Board
PI	Preliminary Injunction
FWD	Final Written Decision

I. INTRODUCTION

Liquidia submits this brief in opposition to UTC's request for a PI.¹

II. ARGUMENT

A. UTC's Delay Demonstrates It Will Not Be Irreparably Harmed

UTC argued it did not delay seeking injunctive relief because (1) it needed to wait until Yutrepia's launch was "immediate" to satisfy DJ jurisdiction, and (2) UTC could not assert the '782 patent in *Hatch-Waxman-II* because it was not listed in the Orange Book for Tyvaso. Hearing Tr. 9:24-10:24; DE 34-37. UTC is incorrect.

1. Immediacy Was Satisfied No Later than Early 2024

UTC claims that DJ jurisdiction did not ripen until the dismissal of the *APA-II* case in May 2025, creating immediacy. Hearing Tr. 11:2-10. In support, UTC relies on *Janssen Products, L.P. v. EVER Valinject GmbH*, 2025 WL 639380 (N.D. Ill. Feb. 27, 2025), a non-binding district court opinion, for the proposition that UTC could not have previously asserted a non-Orange Book listed patent, like the '782 patent, in a Hatch-Waxman case. Hearing Tr. 9:14-10:24. The Federal Circuit, however, has long held that non-Orange Book listed patents can be asserted in a Hatch-Waxman litigation, like *Hatch-Waxman-II*. In *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997), the court permitted assertion of a non-Orange Book listed patent in a Hatch-Waxman case based on "imminent FDA approval" and threats of future infringement. *Id.* UTC alleged these very facts more than a year ago.

¹ Liquidia incorporates by reference its opposition to UTC's TRO request. DE 36.

First, on February 26, 2024, in its *Hatch-Waxman-II* PI brief, UTC asserted Yutrepia's launch was imminent upon the March 31, 2024 expiration of UTC's exclusivity, and that Liquidia intended to launch despite UTC's patents. DE 34-9 at 1, 4. UTC's February 2024 allegations satisfy *Glaxo*'s immediacy requirement, evidencing UTC had DJ jurisdiction to assert the '782 patent in *Hatch-Waxman-II* in early 2024.

Second, UTC did not require DJ jurisdiction because its Complaint alleges current infringement, not just imminent infringement, based on Liquidia's ASCENT trial. DE 1, ¶36; DE 1-6. UTC was aware of the ASCENT trial as early as November 2023, when the ASCENT trial was "first posted" on clinicaltrials.gov, thus UTC could have asserted the '782 patent, outside of Hatch-Waxman, then.² Ex.A

Third, UTC is incorrect that it could only sue on Tyvaso Orange Book patents. Hearing Tr. 9:24-10:24. "[T]he requirements for jurisdiction in the district courts are met once a patent owner alleges that another's filing of an ANDA infringes its patent under § 271(e)(2)." *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012) (holding that Orange Book listing is not a prerequisite to asserting a patent under § 271(e)(2), as jurisdiction arises once the patentee alleges that an FDA filing infringes its patent); *Glaxo*, 110 F.3d at 1571. These facts, viewed under the appropriate law, establish UTC could have sued sooner, but choose to wait, thereby defeating its PI request. *Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005); DE 36, 6-7.

² At least UTC became aware of the ASCENT trial no later than October 30, 2024, when it asserted infringement based on ASCENT in *Hatch-Waxman-II*.

B. UTC's General Business Allegations Do Not Establish Irreparable Harm

UTC's irreparable harm is contradicted by the record, including its own public statements evidencing no harm, which it was aware of but did not address in its PI Motion or during oral argument. *See* DE 36, 10-13; DE 35, ¶¶85-99. Belatedly, in its bond letter, UTC states “[i]rreparable harm does not require that a business as a whole suffer catastrophic loss.” DE 45, 1. Here, UTC executives have said it will suffer *no* loss.

Despite UTC's allegation that Liquidia will take “significant market share sales[,]” (*id.*), just two weeks ago UTC executives said Liquidia “is not a commercial threat” and would “only take “5% share.” DE 34-23 at 1. Days earlier, Dr. Rothblatt, UTC's CEO, said new entrants like Yutrepia do not “steal the market” and expressed confidence in continued growth “for many years to come.” DE 34-22 at 10; DE 35, ¶98. 5% is hardly “significant” and thus UTC's unsupported claims are not sufficient to show irreparable harm. *See Pentair Water Pool & Spa v. Hawyard Indus.*, 2012 WL 194403, at *10 (E.D.N.C. Jan. 23, 2012).

Moreover, in 2024, more than half of UTC's total revenue came from various formulations of treprostinil. DE 35, ¶21. And UTC projects continued growth for Tyvaso and Tyvaso DPI through 2035, expressly assuming Yutrepia would begin competing with UTC in 2024. DE 34-27; DE 35, ¶¶79-82; Hearing Tr. 52:5-13. UTC's current forecasts, coupled with UTC executive statements such as Yutrepia “does not challenge [UTC's] projected double-digit growth[,]” prove UTC will experience no harm, let alone irreparable harm. DE 34-28 at 3; DE 35, ¶88.

1. Judge Andrews Considered and Rejected Price Erosion

UTC argues that price erosion will be immediate and irreparable. DE 45, 1. UTC attempts to distinguish this case from Judge Andrews's prior rejection of price erosion as speculative, arguing that "new" evidence supports its claims. *See* Hearing Tr. 33:25-34:24; DE 34-19 at 19-21. The evidence is old and was given to Judge Andrews.

UTC and Dr. Selck cite testimony from UTC's David Barton regarding his discussions with [REDACTED] *See* DE 34-19 at 19-21; DE 9, ¶¶68-81. But those discussions, already cited by Dr. Selck in his *Hatch-Waxman-II* PI declaration, occurred in 2023, and were before Judge Andrews. *See e.g.*, DE 9, ¶68 n.158; DE 34-19 at 19-21; Ex.B, ¶¶62, 64, 66, 73-74. There is no "new" evidence. Dr. Selck, today, does not quantify any actual price erosion, stating only that UTC [REDACTED] [REDACTED] DE 9, ¶68 (emphasis added). Nowhere does he identify how much prices have or will fall. Because UTC has not shown that anything has changed since Judge Andrews rejected its claim of price erosion in *Hatch-Waxman-II*, UTC's allegations of irreparable harm should be denied.

C. UTC Cannot Demonstrate Likelihood of Success

UTC must show it will likely prove Yutrepia infringes valid claims of the '782 patent. *Entegris, Inc. v. Pall Corp.*, 490 F.3d 1340, 1351 (Fed. Cir. 2007). Liquidia has raised "substantial questions" about infringement and validity, warranting denial of UTC's Motion. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997).

1. Yutrepia does not infringe

Yutrepia does not infringe any claim of the '782 patent because there is no “coordinated actuation of the dry powder inhaler with each breath[.]” ’782 patent, cl.1; DE 36, 20-21. UTC asserts *all* DPI’s, “by definition,” “coordinat[e]” inhalation and actuation because they are breath-actuated. Hearing Tr. 16:14-23; 18:11-14; 19:3-7; 79:14-18; 80:6-13. But UTC’s construction renders “coordination” superfluous, because UTC contends inhaling *is* actuation. See e.g., *Wasica Finance GmbH v. Cont’l Auto. Sys., Inc.*, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017) (“It is highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous.”); Hearing Tr. 79:15-18 (“breathing in, *causing* the actuation of the device[.]”) (emphasis added); *id.* 77:1-16. UTC’s counsel was unable to reconcile its construction with the prior art making clear that breath-actuated “DPIs obviate coordination of actuation and inspiration[.]” Hearing Tr. 79:24-80:23; DE 34-6 at 1304-05; *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996) (explaining that “prior art references may also be more indicative of what all those skilled in the art generally believe a certain term means” than extrinsic expert testimony). Yutrepia’s breath-actuated DPI “obviates” coordination and does not infringe.

2. There is a substantial question as to validity

UTC argued that the PTAB’s FWD invalidating the '793 patent does not raise a substantial question of invalidity for two reasons, neither one compelling. First, UTC argued that the Examiner allowed the '782 patent despite having the PTAB’s Institution Decision, which UTC incorrectly alleges is “a mirror” of the FWD. Hearing Tr. 67:9-20.

On the contrary, the FWD: (1) presents a more fulsome analysis of the parties' arguments (*compare* Ex.C at 27-30, 32-34, *with* DE 34-16 at 14-17, 18-21); (2) addresses additional arguments by UTC (*see e.g.* DE 34-16 at 22-30 (refuting UTC's objective indicia of nonobviousness)); (3) relies on evidence not available at institution (*see e.g.*, DE 34-16 at 20 (relying on deposition testimony from UTC's expert, Dr. Waxman)); and (4) applies a different legal standard (*compare* Ex.C at 43 ("a reasonable likelihood that it will prevail in showing that at least one of the challenged claims is unpatentable") with DE 34-16 at 46 ("preponderance of the evidence that claims [] are unpatentable"))).

Second, UTC argued the '782 claims are valid because they include a "3-hour limitation" not addressed in the IPR. Hearing Tr. 68:23-69:19. But Examiner Schmitt, who allowed the '782 claims, later found this limitation obvious over the same prior art relied on by the PTAB to invalidate the '793 patent—JESC. *See* DE 34-38 at 11-12. For at least these reasons there is a substantial question of validity sufficient to defeat UTC's Motion.

III. CONCLUSION

For the foregoing reasons, UTC's Motion should be denied.

Dated: May 30, 2025

Respectfully submitted,

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CERTIFICATE OF WORD COUNT

The undersigned certifies that this brief, excluding the caption, signature lines, certificates of service, cover page, tables and indexes, contains 1,500 words, as determined using the standard word count feature of the Microsoft Word program. As such, this brief is in compliance with Rule 7.3(d)(1) of the Local Rules for the Middle District of North Carolina, in that it contains less than 6,250 words.

Dated: May 30, 2025

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CERTIFICATE OF SERVICE

I hereby certify that on May 30, 2025, I electronically filed the foregoing with the United States District Court for the Middle District of North Carolina using the Court's CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the CM/ECF system.

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